SLOVENSKI STANDARD
SIST EN ISO 81060-1:2012

01-september-2012

Nadomešča:
SIST EN 1060-1:2000+A2:2010
SIST EN 1060-2:2000+A1:2010

Neinvazivni sfigmomanometri - 1. del: Zahteve in preskusne metode za neavtomatizirane vrste merjenja (ISO 81060-1:2007)

Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)

Nicht invasive Blutdruckmessgeräte - Teil 1: Anforderungen und Prüfverfahren der nicht-automatisierten Bauart (ISO 81060-1:2007)

Sphygmomanomètres non invasifs - Partie 1: Exigences et méthodes d'essai pour type à mesurage non automatique (ISO 81060-1:2007)

Ta slovenski standard je istoveten z: **EN ISO 81060-1:2012**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN ISO 81060-1:2012 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 81060-1

May 2012

ICS 11.040.10

Supersedes EN 1060-1:1995+A2:2009, EN 1060-2:1995+A1:2009

English Version

Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)

Sphygmomanomètres non invasifs - Partie 1: Exigences et méthodes d'essai pour type à mesurage non automatique (ISO 81060-1:2007)

Nicht invasive Blutdruckmessgeräte - Teil 1: Anforderungen und Prüfverfahren der nicht-automatisierten Bauart (ISO 81060-1:2007)

This European Standard was approved by CEN on 28 April 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 81060-1:2012: E

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Foreword

The text of ISO 81060-1:2007 has been jointly prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and Sub-Committee IEC/SC 62D “Electromedical equipment” of the International Electrotechnical Commission (IEC) and has been taken over as EN ISO 81060-1:2012 by Technical Committee CEN/TC 205 “Non-active medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2012, and conflicting national standards shall be withdrawn at the latest by May 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 1060-1:1995+A2:2009, EN 1060-2:1995+A1:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

EN ISO 81060 consists of the following parts, under the general title *Non-invasive sphygmomanometers*:

— *Part 1: Requirements and test methods for non-automated measurement type*

— *Part 2: Clinical validation of automated measurement type*

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 81060-1:2007 has been approved by CEN as a EN ISO 81060-1:2012 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices *(1/3)*

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.4.3, 8.3, 8.4, 8.5	7.2	Prevention of risks related to mercury leakage and spillage only. Packaging is not addressed. Design and manufacture are addressed via tests on finished products.
8.3, 8.4, 8.5	7.5 (first sentence)	Only prevention of risks due to mercury leakage
10.1, 10.2	8.1	Only reduction of the risk of infection to a commonly accepted level is addressed (not “as far as possible”). Manufacturing processes are not addressed. Easy handling is not addressed.
10.3	8.4	
4.7 b)	8.7	ER 8.7 is partially addressed.
6.2, 7.1.2, 7.2.4, 7.2.5, 7.2.6, 12.2.1 c)	9.1	
6.3, 7.2.3	9.2 (1st indent)	Prevention of injury due to rough surfaces and prevention of injury due to excessive pressure are addressed.
6.2, 6.3, 6.4	9.2	ER 9.2 is partially addressed.
6.2	9.3	Only addressed for electrical devices via IEC 60601-1, Clauses 11 and 13.
4.4 e), 6.2, 7.1.1, 7.1.2, 7.2.1, 7.2.2, 7.4, 8.1, 9, 12.2.1 b), 12.2.1 l), 12.2.1 n), 12.2.1 q), 12.3.b), 12.3.c)	10.1	For electrical devices, see also IEC 60601-1 Clause 12, as required in Clause 6.2 of the present standard.

Table ZA.1 — *(2/3)*

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.2, 4.3, 4.4 e), 4.5, 6.2,	10.2	For electrical devices, see also IEC 60601-1 Clauses 7 and 12, as required in Clause 6.2 of the present standard.
4.1, 6.2	10.3	For electrical devices, see also IEC 60601-1 subclause 7.4.3, as required in Clause 6.2 of the present standard.
6.2	12.1	Only addressed for electrical devices via IEC 60601-1, Clause 14.
6.2	12.1 a)	Only addressed for electrical devices via IEC 60601-1, Clause 14.
6.2	12.5	Only addressed for electrical devices via IEC 60601-1, Clause 17.
6.2	12.6	Only addressed for electrical devices via IEC 60601-1, Clause 8.
6.2, 6.3	12.7.1	For electrical devices, see also IEC 60601-1 Clauses 9 and 15, as required in Clause 6.2 of the present standard.
6.2	12.7.2	Only addressed for electrical devices via IEC 60601-1, Clause 9.
6.2	12.7.3	Only addressed for electrical devices via IEC 60601-1, Clause 9.
6.2	12.7.4	Only addressed for electrical devices via IEC 60601-1, Clauses 8 and 15.
6.2	12.7.5	Only addressed for electrical devices via IEC 60601-1, Clause 11.
12.2.1 f), 12.2.1 h)	12.9	
4, 6.2, 12	13.1	
4.4, 4.7, 12.2.1 h)	13.2	
4.4 a), 6.2, 12.1	13.3 a)	The part of ER 13.3.a) relating to the authorized representative is not addressed.
4.4 b), 4.7 a)	13.3 b)	
4.7 b)	13.3 c)	

Table ZA.1 — *(3/3)*

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.4 c)	13.3 d)	The presumption of conformity is only provided if the batch number is preceded by the word “LOT”.
4.7 c)	13.3 e)	
4.7 d)	13.3 f)	The presumption of conformity is only provided if the indication of single use is consistent across the Community.
4.7 e)	13.3 i)	
4.6 a), 4.6 b)	13.3 j)	
12.2.1 m), 12.2.1 n)	13.3 k)	
6.2	13.3 l)	
4.7 b)	13.3 m)	
4.6 b), 4.7 f), 12.2.1 a)	13.4	
4.4 b), 4.4 c), 6.2	13.5	
12.1, 12.2.1 g), 12.2.1 p), 12.2.1 r), 12.2.1 s)	13.6 a)	This Essential Requirement is partially addressed.
12.2.1.e), 12.2.1 k), 12.2.1 l), 12.2.4	13.6 c)	
12.2.1 e), 12.2.1 j), 12.2.1 k), 12.2.1 o), 12.2.1 s), 12.2.3	13.6 d)	
6.2	13.6 f)	ER 13.6 f) is addressed only for electrical devices via IEC 60601-1.
12.2.2	13.6 h)	The part of ER 13.6 h) relating to “single use” is not addressed.
12.2.1 c), k)	13.6 i)	For electrical devices, see also IEC 60601-1 Clause 7, as required in Clause 6.2 of the present standard.
4.4 d), 6.2, 12.2.1 t), 12.2.5	13.6 n)	

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

NOTE Table ZA.2 is only applicable to electrical devices.

Table ZA.2 – Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.5, 6.2	1.2.2	Only partly addressed
6.2	1.5.1	
7.2.6, 7.3	1.5.4	Errors of fitting are only reduced to a commonly accepted level, but are not made “impossible”
6.2	1.5.5	
6.2	1.5.6	
6.2	1.5.7	
6.2	1.6.3	Only partly addressed

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 81060-1

First edition
2007-12-01

Non-invasive sphygmomanometers —

Part 1: Requirements and test methods for non-automated measurement type

Sphygmomanomètres non invasifs —

Partie 1: Exigences et méthodes d'essai pour type à mesurage non automatique

Reference number
ISO 81060-1:2007(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 81060-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

ISO 81060 consists of the following parts, under the general title *Non-invasive sphygmomanometers*:

— *Part 1: Requirements and test methods for non-automated measurement type*

The preparation of a second part covering clinical evaluation for the automated measurement type is planned.

For automated measurement type non-invasive sphygmomanometers, see IEC 60601-2-30 [7].